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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,688	02/10/2004	Gregory B. Altshuler	105090-0232	3815
21125 7590 12/06/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER JOHNSON III, HENRY M	
			ART UNIT 3739	PAPER NUMBER
			NOTIFICATION DATE 12/06/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

# Office Action Summary

Application No.

10/776,688

Applicant(s)

ALTSHULER ET AL.

Examiner

Henry M. Johnson, III

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-10,13,15-20,22-24,26-30 and 48-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-6,8-10,13,15-17,19,20,22-24,26-30 and 48-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 053107.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2007 has been entered.

***Response to Arguments***

Applicant's arguments filed October 21, 2007 have been fully considered but they are not persuasive. The definition provided by the Applicant for photodynamic therapy is narrowly restricted to exogenous agents, when the light therapy may use either endogenous or exogenous elements that absorb specific wavelengths. Widely known treatments include acne using endogenous porphyrins and bilirubin. Further, the method steps of Biel in claim 13 do not include any administration of an agent and have the treatment parameters as required by the Applicant and would therefore yield the same results. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993).

It is noted that the Applicant's reply documentation included three different application numbers (10/77668, 10/776686 & 10/776688). For example, the claim list was marked for application 10/776686.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "said treatment sessions" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "said treatment sessions" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 8, 10, 13, 15-17, 20, 22, 26-29 and 48-51 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent 6,159,236 to Biel. Biel discloses a method of using a light emitting treatment device in a body, comprising positioning the member to direct light at the treatment site and activating the light source for a period of time to emit energy at the treatment site for photodynamic therapy. Viruses, fungi and bacteria are specifically targeted (abstract). The one or more light sources are configured to provide light wavelengths ranging from about 450 nanometers to

about 850 nanometers, a light dosage rate ranging from about 0 mW/cm<sup>2</sup> to about 150 mW/cm<sup>2</sup> and a light dose ranging from 0 J/cm<sup>2</sup> to about 300 J/cm<sup>2</sup> (Col. 2, line 66 to Col 3, line 11). The wavelengths overlap those disclosed by the applicant as being absorbed by endogenous agents. Biel teaches selecting the wavelength based on the target agent. Independent claim 13 of Biel has no step of introducing any exogenous agent, thus implying an endogenous target. The radiation of pathogens would inherently produce the same results as those claimed. The body cavity may be an oral cavity (Fig. 4). Times within the cited treatment times are inherent to achieve the fluence disclosed by Biel with the powers disclosed. As noted above, PDT only requires light absorption by an agent or chromophore without limitation as to its being exogenous or endogenous.

Regarding claims 2, 3 and 50-51, no method steps are associated with the location of the light receptors or a specific light receptor or a specific pathogen. To be further limiting, a further step is required.

Regarding claims 8 and 28, the fluences of Biel are within the range of the Applicant for killing pathogens.

Regarding claim 10, no step impacts how the receptor responds to non-visible light.

Regarding claim 27, the power and fluences allow treatment times well in excess of the time required for blood to circulate through a body.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,159,236 to Biel as applied to claims 1 and 20 above, and further in view of U.S. Patent 6,887,260 to McDaniel. Biel is discussed above, but does not teach specific target acceptors. McDaniel teaches light treatment of acne by targeting of the native (endogenous) porphyrins. It would have been obvious to one skilled in the art to target a known endogenous agent associated with the condition to be treated as taught by McDaniel and irradiating the area as taught by Biel.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,159,236 to Biel as applied to claim 1 above, and further in view of U.S. Patent 6,135,774 to Hack et al. Biel is discussed above, but does not teach the use of diagnostic signals. Hack et al. teach a device for detecting fluorescence from teeth that may be used as a measure of whiteness thus providing a teaching of diagnostic feedback during the oral application of light radiation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use diagnostic feedback as taught by Hack et al. in the method of Biel as feedback during a light treatment process is well known and obvious.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,159,236 to Biel as applied to claim 20 above, and further in view of U.S. Patent 6,026,828 to Altshuler. Biel is discussed above, but does not teach wavelengths below 450 nanometers. Altshuler teaches a device for providing radiation to an oral cavity and discloses that it has been found that there is antibacterial and anti-inflammatory action of UV (330-380 nm), blue (440-450 nm) and green (514-590 nm) radiation. In addition the red (630-640 nm) and near IR (830-1300 nm) radiation also provides profilaxis and caries treating influence (Col. 2, lines 7-11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the lower wavelengths as taught by Altshuler in the method of Biel as Altshuler specifically teaches the benefits of using such wavelengths in radiation in an oral cavity.

#### ***Allowable Subject Matter***

Claim 18 is allowed.

#### ***Conclusion***

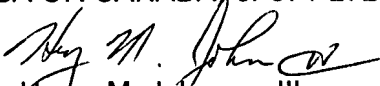
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Henry M. Johnson, III  
Primary Examiner  
Art Unit 3739